K 063237

Section 5
510 (k) SUMMARY

DEC - 8 2006

Applicant: Bisco, Inc.
1100 W. Irving Park Road
Schaumburg IL, 60193
Contact Person: Benjamin Lichtenwalner
Tel: 847-534-6146
Fax: 847-534-6111
Date Prepared: October 25, 2006

Trade Name: **TheraCal LC**
Common Name: Liner & Pulp Capping Material
Classification/Name: Liner, Cavity, Calcium Hydroxide
Class II per 21 CFR 872.3250

Description of Applicant Device:

TheraCal LC is a light-cured resin-based, mineral trioxide aggregate (MTA) filled, liner designed to perform as a barrier and to protect the dental pulpal complex. **TheraCal LC's** precise placement allows its use in all deep cavity preparations. The light-cured set permits the practitioner immediate placement and condensation of the restorative material. Its proprietary formulation allows for a command set with a visible light curing unit while maintaining ease of placement due to thixotropic properties. The proprietary hydrophilic resin formulation creates a stable and durable liner or base

Intended uses of Applicant Device:

TheraCal LC is a light-cure resin-based, mineral trioxide aggregate (MTA) filled, liner designed to be used as a liner and pulp capping material. Its physical properties and uses are similar to the predicate device.

Predicate Devices: Prisma VLC Dycal cleared under (K922721) dated July 23, 1992.

Significant Performance Characteristics:

	Prisma VLC Dycal	**TheraCal LC**
Intended use	Liner & Pulp Capping Material	Liner & Pulp Capping Material
Chemical composite	Light-cured, Calcium Hydroxide filled, resin liner	Light-cured, MTA (Mineral Trioxide Aggregate) filled, resin liner
Mechanical /physical properties	Low viscosity, dispensable composite	Low viscosity, dispensable composite

Side by side comparisons of **TheraCal LC** to the predicate device **Prisma VLC Dycal** clearly demonstrates that the applicant device is substantially equivalent to the legally marked device. **TheraCal LC** was tested for biocompatibility and it was found to be non-toxic. It is concluded that the information supplied in this submission has proven the safety and efficacy of **TheraCal LC**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Benjamin Lichtenwalner
Regulatory Affairs Manager
Bisco, Incorporated
1100 West Irving Park Road
Schaumburg, Illinois 60193

DEC - 8 2006

Re: K063237
Trade/Device Name: TheraCal LC
Regulation Number: 21 CFR 872.3250
Regulation Name: Calcium Hydroxide Cavity Liner
Regulatory Class: II
Product Code: EJK
Dated: October 25, 2006
Received: October 26, 2006

Dear Mr. Lichtenwalner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

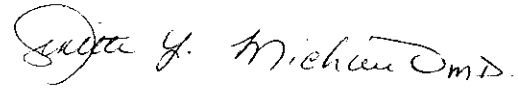
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K063237

Device Name: TheraCal LC

Indications for Use:

1. Liner
2. Pulp capping agent

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
(510(k) Number) K063237